

# **Coal Combustion Products and REACH**

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## **1 Introduction**

On 1st June 2007, the REACH-Regulation (Registration, Authorisation, Evaluation and Restriction of Chemicals) entered into force. The overriding goal of the regulation is to improve the protection of human health and the environment from the risks of chemicals while enhancing the competitiveness of the EU chemicals industry. By this, all chemicals manufactured in or imported into the EU have to be registered at the European Chemicals Agency (ECHA). The registration requires information on the properties and the potential risks of the substances.

As Coal Combustion Products (CCPs) are mainly utilised in the building material industry, in civil engineering and in road construction they are placed on the market and for many applications, i.e. those which are not covered by waste legislation and served with (by-) products, they are subject to REACH. By this, each producer or importer of coal combustion products (CCPs) placed on the market as construction materials have to pre-register and to register their substances. The pre-registration requires information on the substance identity, the tonnages and the name and address of the producer. The registration requires i.a. comprehensive information about toxicology and ecotoxicology of the substances.

In Europe, non registered substances can not be placed on the market after 1st June 2008 any more! For CCPs, since they are already registered in the European Inventory of the Existing Commercial Chemical Substances (EINECS) the deadline for registration is extended to 1 December 2010. This is only true if the producer pre-register in the period of 1st June to 1 December 2008! In special cases also late pre-registration by 1<sup>st</sup> November 2009 is possible.

This paper deals specifically with the relation of REACH and CCPs and will highlight the work of pre-registration and joint registration of CCPs.

## **2 REACH Background and Development**

On 27 February 2001 the Commission issued a White Paper on a Strategy for a future Chemicals Policy. This has subsequently been developed and extensively discussed with major stakeholders, resulting in the release on 29 October 2003 of the Commission's proposal (REACH - Registration, Authorisation, Evaluation and Restriction of Chemicals).

Under REACH enterprises that manufacture or import more than one tonne of a chemical substance per year are required to register it in a central database. REACH will furthermore give greater responsibility to industry to manage the risks from chemicals and to provide users in the supply chain with safety information on the substances.

The European Parliament first reading of the REACH proposal was finalised on the 17th of November 2005 and the Council reached a political agreement on the 13th of December 2005. The REACH Regulation was formally adopted on 18 December 2006 by the Council of Ministers following the vote in second reading of the European Parliament on 13 December 2006. REACH entered into force on 1 June 2007.

The main task of the European Chemicals Bureau in the interim period until the entry into force of REACH was to develop technical guidance and IT tools that will enable the industry and authorities to administer the legislation effectively from the start. This was done through a number of REACH Implementation Projects (RIPs) that were carried out in close collaboration between the Commission Services and stakeholders of REACH. Most of these projects have been finalised and handed over to the European Chemicals Agency (ECHA), which is formally responsible for making guidance available.

The European Chemicals Agency (ECHA) was created on 1 June 2007 in Helsinki and is responsible for managing the registration and evaluation processes for chemical substances to ensure consistency in the European Union. It will also have an important role in the authorisation and restriction processes under REACH. All information regarding REACH is placed at the website (<http://echa.europa.eu>).

30.12.2006:	REACH regulation was published in the official journal of the EU
01.06.2007:	REACH entered into force
01.06.2008:	European Chemicals Agency (ECHA) becomes operational
01.06.2008 – 01.12.2008	Six-month window for companies to pre-register “phase-in” substances
by 01.06. 2008:	European Commission must adopt a regulation setting the fees payable by firms under various parts of REACH
by 01.12. 2008:	Commission must review criteria for identifying persistent and bioaccumulative substances, a class of dangerous chemicals targeted by the authorisation procedure. By the same date the commission must define the criteria that will allow some firms to omit some testing requirements under REACH
on 01.01.2009	Chemicals agency will publish the list of pre-registered substance
by 01.06.2009	Chemical Agency will make its first recommendations on priority substances to be included under the authorisation requirement
by 01.12.2010	End of registration of pre-registered phase-in substances (> 1000 t)
01.06.2018:	End of SIEF operations

Table 1 Important deadlines within REACH

The REACH regulation developed from existing systems for chemicals. Within REACH Registration is synonym for submitting a registration for a substance by the manufacturer, the importer of a substance or the producer or importer of an article. A registration shall include a technical dossier including and a chemical safety report.

Evaluation is synonym for information on the manufacture and use(s) of the substance; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories; the classification and labelling of the substance; guidance on safe use of the substance.

Authorisation is synonym for providing submission numbers and checking the completeness of registration dossiers as well as examination or rejection of proposed test procedures herein by the Agency.

Chemicals mean substances on their own, in preparations or in articles. Within REACH "substances" (chemicals), "preparations" (consist of different chemicals) and "articles" (products, e.g. cups, computers...) will be regulated. Only substances (on their own) have to be registered. Preparations and articles do not need a registration. Exempted from REACH are those materials which are chemically not modified. Also waste is exempted.

The group of "substances" is subdivided to "non phase-in" and "phase-in" substances. REACH provides an extended time period for the register of "phase-in" substances, a precondition is that they are pre-registered. The basic definition for a "phase-in" substance with regard to CCP is that they are listed in EINECS (European Inventory of Existing Commercial Chemical Substances).

End of the 1970th only a few chemicals had been regulated by special regulations (drugs, pesticides, explosives...) and most of the common chemicals placed on the market were not regulated! By this, no information was available how many chemicals were commercially placed on the market, nor in which amounts or in what kind of applications this chemicals were used, nor how many new chemicals have been added to the market every day. To ensure a high level of protection of human health and the environment by using chemicals this situation was to be changed. A general regulation was needed to regulate (test, evaluate, restrict, label ...) all commercial chemicals which are not being regulated by other laws. A first step was to focus on „new chemicals“, which have not been placed on the EU-market limited by a special deadline. Already marketed chemical substances – so called „existing“ commercial chemical substances“ - had to be listed within the deadline, not to be new!

The **E**uropean **I**nventory of **E**xisting commercial **C**hemical **S**ubstances (**EINECS**) is based on the **E**uropean **C**ore **I**nventory (**ECOIN**) to which supplementary substance reporting could be made by industry (according criteria for reporting substances for EINECS). ECOIN was composed by blending different lists of chemicals presumed to be on the European market. By this, even coal combustion products (CCPs) have been listed. In total more than 100.000 substances are listed in the EINECS - including CCPs-. This list is „frozen“. No more substances can be added to it or removed from it. With only view exemptions those chemicals have not been judged due to risk assessment.

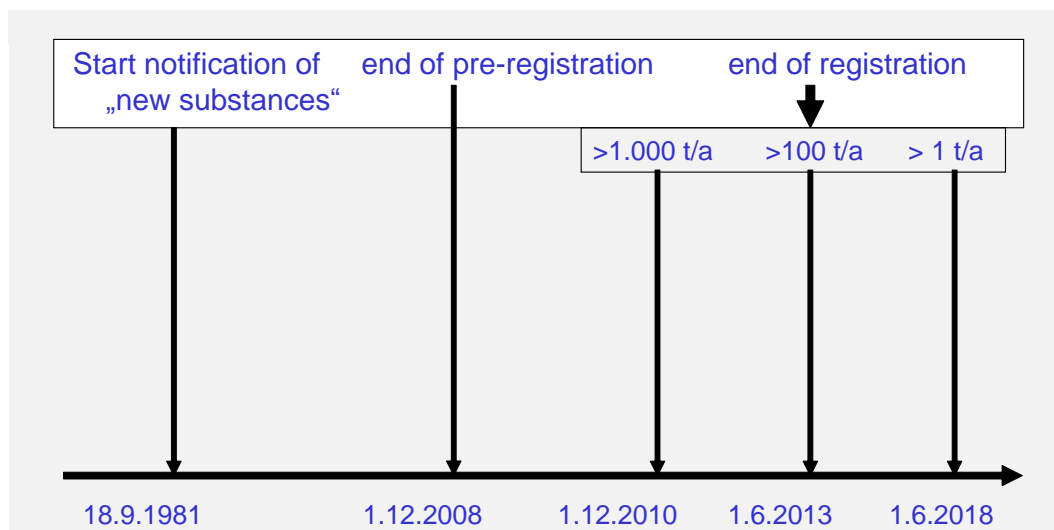


Figure 1: Deadlines for notification (ELINCS) and registration (REACH) of chemicals

Since September 18, 1981 all „new chemicals“ have to be tested, evaluated and notified before approval of marketing in the EU. They are listed in the European List of Notified Chemical Substances (ELINCS). By now, more than 4000 substances are listed in ELINCS being assumed to be safe.

All information about listed chemicals can be checked in ESIS (European chemical Substances Information System).

Beside the EINECS numbers mostly all chemicals also can be addressed with a CAS (Chemical Abstract Service) number. The CAS REGISTRY is the most authoritative collection of disclosed chemical substance information. Researchers, regulatory agencies, information and legal professionals are examples of individuals and organizations who rely on registry for the most accurate and current chemical substance information. A CAS registry number (sometimes known as a "CAS Number") is the unique chemical substance identifier that enables efficient links to the broad chemical literature and which is also used as a substance identifier in commerce (e.g. in regulatory registrations).

New CAS registry numbers are assigned when new substances are reported in the literature and enter the CAS databases, and when requested for commercial registration purposes. It covers substances identified from the scientific literature from 1957 to the present, with additional substances going back to the early 1900s. The latest CAS registry number® and substance count 46,726,072 organic and inorganic substances and 60,936,919 sequences (status May 11, 2009).

The International Union of Pure and Applied Chemistry (IUPAC) serves to advance the worldwide aspects of the chemical sciences and to contribute to the application of chemistry in the service of Mankind. As a scientific, international, non-governmental and objective body, IUPAC can address many global issues involving the chemical sciences. The IUPAC-recommendations is the definitive guide for scientists working in academia or industry, for scientific publishers of books, journals and databases, and for organisations requiring internationally approved nomenclature in a legal or regulatory environment.

With regard to REACH also the IUCLID database is of importance. This is a management system for the administration of data on chemical substances. This IUCLID Chemical Data Sheets Information System provides extracts of data from the IUCLID on high production volume chemicals reported by European Industry in the frame of the European existing chemicals risk assessment programme. There are listed 2604 current substances with available Chemical Data Sheets. A Chemical Data Sheet contains data on general information, physico-chemical data, environmental fate and pathways, ecotoxicity, toxicity and references.

### 3 Coal Combustion Products

Coal Combustion Products (CCPs) are produced with the production of electricity and steam in coal-fired power plants. In 2006, about 61 million tonnes of CCPs were produced in Europe (EU15). The production in all the European members states is estimated to be about 100 million tonnes. They are mainly utilised in the building material industry, in civil engineering, in road construction, for construction work in underground coal mining as well as for recultivation and restoration purposes in open cast mines. The majority of the CCPs are produced to meet certain requirements of standards or other specifications with respect to utilisation in certain areas.

CCPs are defined as follows:

- **Fly Ash (FA, PFA)** is obtained by electrostatic or mechanical precipitation of dust-like particles from the flue gases of furnaces fired with coal or lignite at 1100 to 1400°C (or 1700 °C in case of wet bottom boilers). Fly ash is a fine powder, which is mainly composed of spherical glassy particles. Depending upon the type of boiler and the type of coal siliceous, silico-calcareous and calcereous fly ashes with pozzolanic and/or latent hydraulic properties are produced.
- **Cenospheres** (floaters) are recovered from the surface of ash disposal ponds and are of similar chemical composition to fly ash. Due to a particle density of less than 1.0 kg/dm<sup>3</sup> they float on water.
- **(Furnace) Bottom Ash (BA)** is a granular material removed from the bottom of dry boilers, which is much coarser than FA though also formed during the combustion of coal.
- **Boiler Slag (BS)** is a vitreous grained material deriving from coal combustion in boilers at temperatures of 1500 to 1700°C, followed by wet ash removal of wet bottom furnaces.
- **Fluidized Bed Combustion (FBC) Ash** is produced in fluidized bed combustion boilers. The technique combines coal combustion and flue gas desulphurization in the boiler at temperatures of 800 to 900°C. FBC ash is rich in lime and sulphur.
- **Semi Dry Absorption (SDA) Product** is a fine grained material resulting from dry flue gas desulphurization with lime acting as the sorbent.
- **Flue Gas Desulphurization (FGD) Gypsum** is a natural gypsum like product which is obtained by wet desulphurization of flue gas and special treatment of the adsorbed products.

<b>EC:</b>	<a href="#">&gt; 268-627-4</a>
<b>CAS:</b>	68131-74-8
<b>Substance Name:</b>	Ashes (residues)
<b>Description:</b>	The residuum from the burning of a combination of carbonaceous materials. The following elements may be present as oxides: aluminum, calcium, iron, magnesium, nickel, phosphorus, potassium, silicon, sulfur, titanium, and vanadium.
<b>EC:</b>	<a href="#">&gt; 270-708-4</a>
<b>CAS:</b>	68476-96-0
<b>Substance Name:</b>	Slags, coal
<b>Description:</b>	Inorganic residuum from the combustion of coal.
<b>EC:</b>	<a href="#">&gt; 300-212-6</a>
<b>CAS:</b>	93924-19-7
<b>Substance Name:</b>	Ashes (residues), cenospheres
<b>Description:</b>	Hollow ceramic spheres formed as a part of the ash in power stations burning pulverized coal. Composed primarily of the oxides of aluminium, iron and silicon and contain carbon dioxide and nitrogen within the sphere.
<b>EC:</b>	<a href="#">&gt; 302-652-4</a>
<b>CAS :</b>	94114-19-9
<b>Substance Name:</b>	Residues, calcium sulfate-contg., flue gas wet desulfurization neutralization
<b>Description:</b>	Residue rich in calcium sulfate obtained during the desulphurisation of flue gases of bituminous coal or oil-fired boilers of power plants. Composed primarily of calcium sulfate with chlorides, fluorides, trace element oxides as well as pure gas dust components from the combustion process.
<b>EC:</b>	<a href="#">&gt; 302-659-2</a>
<b>CAS:</b>	94114-25-7
<b>Substance Name:</b>	Slimes and Sludges, power-plant cooling water softening, calcium carbonate-contg.
<b>Description:</b>	Filter sludge formed during the treatment of surface water for cooling purposes in a power plant operation followed by removal of hydrogen carbonates. Composed primarily of calcium carbonate, with the addition of iron and/or aluminium oxides, chlorides, sulfates and fluorides of the alkali and alkaline earth elements and organic components from the raw water.

Table 2 EC and CAS numbers of CCPs (phase-in substances)

As CCPs are listed in EINECS (European Inventory of Existing Commercial Chemical Substances) they can be defined as “phase-in substances” according to REACH (see table 2). By this, they can be registered by 1<sup>st</sup> December 2010 provided that the producer pre-registered in the period of 1st June to 30 November 2008! New producers or producers/importers placing the material on the market for the first time can also do so by 1<sup>st</sup> December 2009 (1 year before deadline for registration).

Even though there are EINECS entries for all types of CCPs it is recommended to check whether a registration is necessary. For by-products as FGD gypsum and at

least ash produced to meet requirements of European and national standards to serve a specific market a registration is required. For materials produced as waste the fields of utilisation should be carefully evaluated regarding their continuation under waste regime (see 4).

#### 4 Exemptions from REACH

Article 2.2 of REACH provides that “*waste as defined in Directive 2006/12/EC of the European Parliament and of the Council is not a substance, preparation or article within the meaning of Article 3 of this Regulation.*” Therefore, REACH requirements for substances, preparations and articles do not apply to waste. This does however not mean that waste is generally exempted from REACH. Further explanation on this is given in the guidance on registration (section 1.6.3.4) and more guidance, in particular on the role of waste related risks in exposure scenarios will be given in the guidance on chemical safety assessment. This includes considerations related to the waste stage of substances as confirmed in Annex I paragraph 5.2.2 where the life-cycle is explicitly said to cover the waste stage. In addition, Annex I paragraph 5.1.1 of REACH also makes it clear that the Risk Management Measures of an Exposure Scenario should “*cover waste management measures to reduce or avoid exposure during waste disposal and/or recycling.*”

The basic definition of materials not being waste, i.e. “by-products” and “end-of-waste-materials” are placed in article 5 and 6 of the Waste Directive which was published in the Official Journal of the European Union on November 22, 2008 and have to be introduced into national law by December 12, 2010.

Article 5 reads as follows:

*A substance or object, resulting from a production process, the primary aim of which is not the production of that item, may be regarded as not being waste referred to in point (1) of Article 3 but as being a by-product only if the following conditions are met:*

- (a) further use of the substance or object is certain;*
- (b) the substance or object can be used directly without any further processing other than normal industrial practice;*
- (c) the substance or object is produced as an integral part of a production process;*  
*and*
- (d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.*

Regarding “end-of-waste-materials” (article 6) it has to be concluded that as soon as a material “ceases to be waste” in a recovery process the REACH requirements apply in principle as to any other material. Where exactly in a recovery process a waste “ceases to be waste” has been subject of long debates in the context of waste legislation. The Institute for Prospective Studies (IPTS) was ordered to develop a scheme for end-of-waste criteria for different waste streams. As a result of this work, and future comitology decisions, some materials currently considered as waste might in future be considered to have ceased to be waste. This would not only mean that

these materials would be outside the scope of waste legislation but also that they would be potentially subject to REACH requirements.

It is important to note that a registered material according to REACH is not automatically a product due to the registration. The decision whether a material is a waste or not has is based on the Waste Directive.

Furthermore, substances listed in Annex IV and Annex V of Regulation (EC) No. 1907/2006 (REACH) are exempted from the registration, evaluation and downstream user provisions of REACH. Annex IV sets out substances that are exempted because sufficient information is known about the substances that they are considered to cause minimum risk because of their intrinsic properties. Annex V sets out substances because registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH.

Based on article 138(4) the Commission has reviewed the annexes IV and V before 1<sup>st</sup> June 2008. The outcome was published in the Official Journal of the European Commission on 9<sup>th</sup> October 2008. It has to be noted that CCPs – also after the Commissions review - are not exempted according to Annex IV or V of the REACH regulation.

## **5 Pre-Registration within REACH**

REACH requires that chemical substances on their own, in preparations and those which are intentionally released from articles have to be registered to the European Chemicals Agency (ECHA). The regulation applies to substances manufactured in, or imported into the EU in annual quantities of 1 ton or more per company, unless the regulation indicates otherwise. The registration is the task of the producer or importer of the substances. Within the registration procedure the producer registers as “legal entity”. For CCPs the legal entity is e.g. the operator of a power plant or the importer of CCPs from outside Europe.

The obligation to register applies from 1<sup>st</sup> June 2008. The producers of chemicals currently on the EU market which meet the definition of phase-in substances had to pre-register the substances between 1<sup>st</sup> June and 1<sup>st</sup> December 2008, in special cases also by 1<sup>st</sup> December 2009. Companies who pre-register their substances can benefit from extended registration deadlines. The deadlines depend on the tonnage band and the hazardous properties of the substance. The deadline for CCPs produced/imported with more than 1000 tonnes is extended to 1<sup>st</sup> December 2010.

### **5.1 Pre-Registration**

Pre-registration requires only limited data and there is no fee associated to it. A pre-registration file for a substance consists of:

- substance Identity: EINECS number, CAS numbers and names of the substance
- envisaged deadline and tonnage band for the registration (for CCPs always > 1000 tonnes and 1. December 2010)
- name and contact information of a contact person or third party representative who will act as the contact point in data sharing



A pre-registrant should also provide when applicable substance identification of any relevant substances which may facilitate the risk assessment and data sharing of the substance

The pre-registration can be performed by the REACH IT or IUCLID software. The substances can be registered as mono-, multi- or UVCB-substance.

A mono-constituent substance is a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w). This is the case for FGD gypsum. Based on long discussion in a project group it was recommended to pre-register FGD gypsum as “calcium sulphate” (EC 231-900-3) and related CAS numbers for all hydration phases. By this all product can be dealt with in the registration dossier.

A multi-constituent substance is a substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration  $\geq 10\%$  (w/w) and  $< 80\%$  (w/w). A multi-constituent substance is the result of a manufacturing process. The difference between preparation and multi-constituent substance is that a preparation is gained by blending of two or more substances without chemical reactions. For CCPs clean SDA product may serve as an example. “Clean” SDA-product means that it is not extracted together with fly ash.

Substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB substances) cannot be sufficiently identified by their chemical composition, because the number of constituents is relatively large and/or the composition is, to a significant part, unknown and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition. Main identifiers are name, source and process.

On January 6, 2009 the ECHA published a first list of substances on its website which were pre-registered by 1<sup>st</sup> December 2008. On March 27, 2008 a press release on an update of the list was published highlighting that around 143.000 substances have been pre-registered by some 65.000 companies.

ECOBA has prepared guidelines for the pre-registration of CCPs and distributed to all producers in Europe. The number of pre-registered parties in the pre-SIEFs relevant for CCPs are given below.

EC Nr	name	nr Pre-registrants
231-900-3 :	calcium sulfate	1575
268-627-4 :	ashes (residues)	1082
300 -212-6 :	ashes (residues) cenospheres	113
270-708-4 :	slags, coal	524
302-652-4 :	SDA (> 10 % ash)	99
-..... :	SDA (multi constituent)	11
297-049-5:	biomass ash	97

## 5.2 Registration

In contrast to the pre-registration, where only brief information for a substance is required (name, "phase-in" substance, tonnage range), the registration requires more detailed information, especially regarding health and safety. An overview of the required physico-chemical, ecotoxicological and toxicological information is given in table 3. These data can be submitted jointly from members in a SIEF (Substance Information Exchange Forum).

A SIEF will be formed for each pre-registered substance with the same identity. Based on the experience with pure chemicals the ECHA first expected that with one EC number only one SIEF is formed and only one dossier is prepared. Meanwhile it was stated that also more than one SIEF may result from one EC number as the definition given with the EC numbers is not precise and may allow wide variations.

Phys.-chem.	Toxicology	Eco-toxicology
Density Melting / Boiling point Water solubility Vapour pressure Partition coefficient Flash point Flammability Explosive properties Surface tension Oxidative properties Granulometry	Acute toxicity (oral) Skin irritation (in vitro) Eye irritation (in vitro) Skin sensitisation Mutagenicity (Ames test)	Akute Daphnia toxicity Algae toxicity Biotic degradation
Stability in organic solvents Identity of degradation products Dissociation constant Viskosity	Skin irritation (in vivo) Eye irritation (in vivo) In-vitro Cytogenicity In vitro mutagenicity (mammalian cells) Acute toxicity (dermal/inhalative) Subacute toxicity (28 d Test) Reproductive/developmental toxicity, (Screening test) Toxicokinetic	Short-term toxicity fish Respiration inhibition test Abiotic degradation Adsorption/desorption
	Subchronic Toxicity (90 d test) Reproduktionstoxizität Developmental toxicity 2-generation-reproductive toxicity	Daphnia reproduction test Long-term toxicity fish Biotic degradation in water Biotic degradation in soil Biotic degradation in sediment Identification of degradation products Bioaccumulation in fish Short-term toxicity invertebrates Soil microorganismen Short-term toxicity plants
	Carcinogenicity	Environmental fate Long-term toxicity terr. invertebrates Long-term toxicity sediment organisms Long-term toxicity birds

**Table 3:** Overview on physico-chemical, ecotoxicological and toxicological information required for REACH registration.

The participants in a SIEF are all pre-registrants (potential registrants, (early) registrants and the data holders). A SIEF has no prescribed legal form, but is a forum to share data and other information on a given substance. Participants in a SIEF are free to organize themselves in consortia or other forms of agreements as they see fit to carry out their obligations under REACH.

After 1 January 2009 a SIEF is formed when pre-registrants have agreed in a pre-SIEF that they manufacture or import the same substance. SIEF members need to nominate a Lead Registrant. They will share and assess data and prepare common parts of the registration (joint submission). For calcium sulfate as well for ashes consortia have been formed by the companies.

Any SIEF member receiving a request for information that involves vertebrate tests must respond within 1 month. Compensation for sharing data is agreed among the

respective SIEF members. All SIEF participants shall react to requests for information from other participants and provide other participants with existing studies upon request. Potential Registrants shall request missing information from other SIEF participants, collectively identify needs for further studies to comply with registration requirements, make arrangements to perform the identified studies and agree on classification and labelling. Data Holders must respond to any query from potential registrants if they hold the data relating to this query and are not entitled to request data.

Most important is a stable form of co-operation as the SIEFs shall remain operational until 1 June 2018.

The information in the full registration dossier will have to provide evidence demonstrating the safe use of the substance. Producers and importers will be required to collect and submit data to ECHA on the hazardous properties of all substances (except polymers and non-isolated intermediates) manufactured or imported into the EU in quantities above 1 tonne per year. In addition, risk assessments and control measure documents will have to be produced for downstream users. This information shall be contained in a chemical Safety Report and Safety Data Sheets (SDS). The joint dossier have to be compiled with the IUCLID software tool, which can be downloaded from the ECHA website. The dossier can be submitted to ECHA by REACH IT and IUCLID.

The complete dossier have to be submitted by the lead registrant to the ECHA for first crosscheck some month before the official registration deadline. If the dossier is announced to be accepted an identification number will be provided to the lead registrant. This number can than be used by each member of that consortium to finalize the legal entity specific registration dossier and to provide it to ECHA. As soon as the dossier is submitted to ECHA the invoice regarding the registration fee can be expected. With the submission of the dossier to the ECHA by the each consortium member the substance is official registered.

After the registration ECHA will start the evaluation phase. There are two types of evaluation that will have to be carried out. A dossier evaluation covers all substances manufactured or imported into the EU over 100 tonnes per year. Any testing proposals to support the dossier put forward by industry as part of their registration package will have to be approved by the Members States and dossiers will have to be kept complete and compliant. For selected substances, for which a risk to health or the environment is suspected, substance evaluation provides a mechanism to require industry to obtain more information. Evaluation may also lead to the conclusion that action should be taken under the restrictions or authorisation procedures. Any Member State can ask for more information to be produced for the Chemical Safety Report.

Acquiring the necessary knowledge on the properties of substances will entail some animal testing. However, REACH has been designed to reduce animal testing to the absolute minimum. Unnecessary tests are avoided due to the obligation to share all data generated through testing on vertebrate animals, and by the provision that for large volume substances testing proposals must be approved by the Agency before new tests on animals will be performed. This will ensure that the endpoints studied are relevant, that the scientific validity of the research is sufficiently high, and that the testing programme does not duplicate other studies.

## 6 European consortia for calcium sulphate and ash

About 3 years ago a project group started to work out details for the pre-registration of FGD-gypsum and ashes. Members of the project group were i.a. representatives of the associations BDEW, VGB, BVK, BV Gips, EuroGypsum and ECOBA. The work of the project group focussed the formation of European consortia for the common registration of calcium sulfate including natural and FGD gypsum and for coal ashes (fly ash, bottom ash, boiler slag). All European producers and importers of coal combustion products were invited to join these consortia and to share the data especially about toxicology and ecotoxicology of the substances.

For calcium sulfate a consortium is formed from producers of natural and FGD gypsum. Lead company and SIEF facilitator is Saint Gobain Gyproc. EUROGYPSUM serves as coordinator.

For ashes two consortia have been formed by now. One consortium is formed with EVONIK STEAG as lead company of the SIEF for ashes and slags, supported by VGB PowerTech and ECOBA. A second consortium was formed by Polish and Czech producers. Meanwhile also a Finnish company offered to form a consortium. As far as the same substances are covered the consortia have to co-operate to produce only one dossier.

## 7 Summary

Coal Combustion Products (CCPs) are being produced in coal-fired power stations which burn either hard or brown coal. They are mainly utilised in the building material industry, in civil engineering, in road construction, for construction work in underground coal mining as well as for recultivation and restoration purposes in open cast mining. By this, they are placed on the market and for many applications they are subject to REACH.

Each producer or importer of coal combustion products (CCPs) placed on the market as construction materials have to pre-register and to register their substances. The pre-registration requires information on the substance identity, the tonnages and the name and address of the producer. The registration requires i.a. comprehensive information about toxicology and ecotoxicology of the substances.

In Europe, non registered substances can not be placed on the market after 1st June 2008 any more! For CCPs, since they are already registered in the European Inventory of the Existing Commercial Chemical Substances (EINECS) the deadline for registration is extended to 1st December 2010. This is only true if the producer pre-register in the period of 1st June to 1st December 2008!

For calcium sulphate and ashes European consortia have been formed. European producers and importers of coal combustion products are invited to join these consortia and to share the data about toxicology and ecotoxicology of the substances.